

**IP13 Rec'd PCT/PTO 08 JAN 2007**

PCT

FORM PTO-1390 (Modified)  
U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE  
(REV 12-2004)

<b>TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A FILING UNDER 35 U.S.C. 371</b>		ATTORNEY'S DOCKET NUMBER  <div style="border: 1px solid black; padding: 2px; text-align: center;">024219-0105</div> U.S. APPLICATION NO. (If known, see 37 C.F.R. 1.5) <div style="border: 1px solid black; padding: 2px; text-align: center;">10/578,903</div>
INTERNATIONAL APPLICATION NO. PCT/AU2004/001592	INTERNATIONAL FILING DATE 11/22/2004	PRIORITY DATE CLAIMED 11/21/2003
TITLE OF INVENTION GI TRACT DELIVERY SYSTEMS		
APPLICANT(S) FOR DO/EO/US Mary Ann AUGUSTIN et al.		
Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:		
<ol style="list-style-type: none"> <li>1. <input type="checkbox"/> This is a <b>FIRST</b> submission of items concerning a filing under 35 U.S.C. 371.</li> <li>2. <input checked="" type="checkbox"/> This is a <b>SECOND</b> or <b>SUBSEQUENT</b> submission of items concerning a filing under 35 U.S.C. 371.</li> <li>3. <input type="checkbox"/> This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (21) indicated below.</li> <li>4. <input type="checkbox"/> The US has been elected (Article 31).</li> <li>5. <input type="checkbox"/> A copy of the International Application as filed (35 U.S.C. 371(c)(2))               <div style="margin-left: 20px;"> <input type="checkbox"/> is attached hereto (required only if not communicated by the International Bureau).  <input type="checkbox"/> has been communicated by the International Bureau.  <input type="checkbox"/> is not required, as the application was filed in the United States Receiving Office (RO/US)             </div> </li> <li>6. <input type="checkbox"/> An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)).               <div style="margin-left: 20px;"> <input type="checkbox"/> is attached hereto.  <input type="checkbox"/> has been previously submitted under 35 U.S.C. 154(d)(4).             </div> </li> <li>7. <input type="checkbox"/> Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3))               <div style="margin-left: 20px;"> <input type="checkbox"/> are attached hereto (required only if not transmitted by the International Bureau).  <input type="checkbox"/> have been communicated by the International Bureau.  <input type="checkbox"/> have not been made; however, the time limit for making such amendments has NOT expired.  <input type="checkbox"/> have not been made and will not be made.             </div> </li> <li>8. <input type="checkbox"/> An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).</li> <li>9. <input checked="" type="checkbox"/> An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)).</li> <li>10. <input type="checkbox"/> An English language translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).</li> </ol>		
Items 11 to 20 below concern other document(s) or information included:		
<ol style="list-style-type: none"> <li>11. <input type="checkbox"/> An Information Disclosure Statement under 37 CFR 1.97 and 1.98.</li> <li>12. <input checked="" type="checkbox"/> An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.</li> <li>13. <input type="checkbox"/> A preliminary amendment.</li> <li>14. <input type="checkbox"/> An Application Data Sheet under 37 CFR 1.76.</li> <li>15. <input type="checkbox"/> A substitute specification.</li> <li>16. <input type="checkbox"/> A power of attorney and/or change of address letter.</li> <li>17. <input type="checkbox"/> A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 37 CFR 1.821 – 1.825</li> <li>18. <input type="checkbox"/> A second copy of the published international application under 35 U.S.C. 154(d)(4).</li> <li>19. <input type="checkbox"/> A second copy of the English language translation of the international application under 35 U.S.C. 154(d)(4).</li> <li>20. <input checked="" type="checkbox"/> Other items or information: Copy of Notification of Missing Requirements.</li> </ol>		

FORM PTO-1390 (Modified)

U.S. APPLICATION NO. (If known, see 37 CFR. 1.5) 10/578,903		INTERNATIONAL APPLICATION NO. PCT/AU2004/001592		ATTORNEY'S DOCKET NUMBER 024219-0105	
--	--	--	--	---	--

The following fees have been submitted:					
21. <input type="checkbox"/> Basic national fee	\$300			\$	
22. <input type="checkbox"/> Examination fee					
If International preliminary examination report prepared by USPTO and all claims satisfy provisions of PCT Article 33(1)-(4)			\$100	\$	
All other situations			\$200		
23. <input type="checkbox"/> Search fee					
Search fee (37 CFR 1.445(a)(2)) has been paid on the international application to the USPTO as an International Searching Authority			\$100		
International Search Report prepared and provided to the Office			\$400		
All other situations			\$500	\$	
<b>TOTAL OF ABOVE 21, 22 and 23 =</b>				\$	
<input type="checkbox"/> Additional fee for specification and drawings filed in paper over 100 sheets (excluding sequence listing or computer program listing filed in an electronic medium). The fee is \$ for each additional 50 sheets of paper or fraction thereof.					
Total Sheets	Extra sheets	Number of each additional 50 or fraction thereof (round up to a whole number)	RATE		
62 - 100 =	0 /50 =	0	x \$250.00	\$	0.00
Surcharge of \$130.00 for furnishing the oath or declaration later than 30 months from the earliest claimed priority date (37 CFR 1.492(e))				\$	0.00
CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE	\$	
Total Claims	16 - 20 =	0	x \$ 50.00	\$	0.00
Independent Claims	3 - 3 =	0	x \$ 200.00	\$	0.00
MULTIPLE DEPENDENT CLAIM(S) (if applicable)			+ \$ 360.00	\$	0.00
<b>TOTAL OF ABOVE CALCULATIONS =</b>				\$	0.00
<input type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27. Fees above are reduced by 1/2.				+	\$ 0.00
<b>SUBTOTAL =</b>				\$	0.00
Processing fee of 130.00 for furnishing the English translation later than 30 months from the earliest claimed priority date (37 CFR 1.492(i)).				\$	
<b>TOTAL NATIONAL FEE =</b>				\$	0.00
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). 40.00 per property				\$	40.00
<b>TOTAL FEES ENCLOSED =</b>				\$	40.00
				Amount to be refunded:	
				charged:	

a. ☐ A check in the amount of \$40.00 to cover the above fees is enclosed.

b. ☐ Please charge my Deposit Account No. 19-0741 in the amount of \$40.00 to cover the above fees. A duplicate copy of this sheet is enclosed.

c. ☒ The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 19-0741. A duplicate copy of this sheet is enclosed.

d. ☒ Fees are to be charge to a credit card. **WARNING:** Information on this form may become public. **Credit card information should not be included on this form.** Provide credit card information and authorization on PTO-2038.

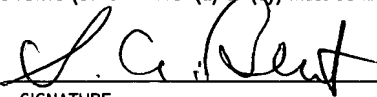
**NOTE:** Where an appropriate time limit under 37 CFR 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the International Application to pending status.

SEND ALL CORRESPONDENCE TO:

Foley & Lardner LLP  
Customer Number: 22428

  
 SIGNATURE  
Stephen A. Bent  
 NAME  
29,768  
 REGISTRATION NUMBER  
January 8, 2007



## UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
 United States Patent and Trademark Office  
 Address: COMMISSIONER FOR PATENTS  
 P.O. Box 1450  
 Alexandria, Virginia 22313-1450  
 www.uspto.gov

U.S. APPLICATION NUMBER NO.	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
10/578,903	Mary Ann Augustin	024219-0105

22428  
 FOLEY AND LARDNER LLP  
 SUITE 500  
 3000 K STREET NW  
 WASHINGTON, DC 20007

INTERNATIONAL APPLICATION NO.	
PCT/AU04/01592	
I.A. FILING DATE	PRIORITY DATE
11/22/2004	11/21/2003

**CONFIRMATION NO. 3340**  
**371 FORMALITIES LETTER**



\*OC000000021279007\*

Date Mailed: 11/20/2006

### NOTIFICATION OF MISSING REQUIREMENTS UNDER 35 U.S.C. 371 IN THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US)

The following items have been submitted by the applicant or the IB to the United States Patent and Trademark Office as a Designated / Elected Office (37 CFR 1.495).

- Copy of the International Application filed on 05/12/2006
- Copy of the International Search Report filed on 05/12/2006
- Copy of IPE Report filed on 05/12/2006
- Information Disclosure Statements filed on 05/12/2006
- Request for Immediate Examination filed on 05/12/2006
- U.S. Basic National Fees filed on 05/12/2006
- Priority Documents filed on 05/12/2006
- Specification filed on 05/12/2006
- Claims filed on 05/12/2006
- Abstracts filed on 05/12/2006
- Drawings filed on 05/12/2006

The following items **MUST** be furnished within the period set forth below in order to complete the requirements for acceptance under 35 U.S.C. 371:

- Oath or declaration of the inventors, in compliance with 37 CFR 1.497(a) and (b), identifying the application by the International application number and international filing date.

**ALL OF THE ITEMS SET FORTH ABOVE MUST BE SUBMITTED WITHIN TWO (2) MONTHS FROM THE DATE OF THIS NOTICE OR BY 32 MONTHS FROM THE PRIORITY DATE FOR THE APPLICATION, WHICHEVER IS LATER. FAILURE TO PROPERLY RESPOND WILL RESULT IN ABANDONMENT.**

The time period set above may be extended by filing a petition and fee for extension of time under the provisions of 37 CFR 1.136(a).

Applicant is reminded that any communications to the United States Patent and Trademark Office must be mailed to the address given in the heading and include the U.S. application no. shown above (37 CFR 1.5)

Registered users of EFS-Web may alternatively submit their reply to this notice via EFS-Web.  
<https://sportal.uspto.gov/authenticate/AuthenticateUserLocalEPF.html>

For more information about EFS-Web please call the USPTO Electronic Business Center at 1-866-217-9197 or visit our website at <http://www.uspto.gov/ebc>.

**If you are not using EFS-Web to submit your reply, you must include a copy of this notice.**

LAMONT M HUNTER

Telephone: (703) 308-9140 EXT 201

PART 1 - ATTORNEY/APPLICANT COPY

U.S. APPLICATION NUMBER NO.	INTERNATIONAL APPLICATION NO.	ATTY. DOCKET NO.
10/578,903	PCT/AU04/01592	024219-0105

FORM PCT/DO/EO/905 (371 Formalities Notice)